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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,370	03/03/2004	Constantine Georgiades	PC32114-03-DCL	4241

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,370	GEORGIADES ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☒ Claim(s) *4 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3 Sep 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a oral composition, classified in class 424, subclass 53 plus.

II. Claim 16, drawn to a method of whitening teeth, classified in class 514, subclass 964.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition may be applied to a strip or dental tray and then applied to the teeth.

Because these inventions are distinct for the reasons given above, the search required for Group I is not required for Group II, and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

a) two water soluble gums: algin, ahginic acid, aginate salts, camitine, carrageenan, dextrin, karaya gum, guar gum, gellan gum, irish moss, veegum (regular),

tara gum, okra gum, gum Arabic, acacia gum, amylopectin or pectina, ghatti gum, natto gum tragacanth gum, xanthan gum, sclerotium gum, kelp, locust bean gum, psyllium see, tamarind gum, destria gum, chitosan, esters thereof, salts thereof and mixtures thereof; and

b) an active agent: whitening agents, antitartar agents, fluoride ion sources, antimicriobial agents, anesthetic agents and mixtures thereof.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 9 and 14 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Darryl Little on January 10, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15, locust bean gum and xanthan gum as the two water-soluble gums, and an antitartar agent as the active agent. Affirmation of this election must be made by applicant in replying to this Office action. Claim 16 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims

Claim Objections

Claims 4 and 10 are objected to because of the following informalities: the end of the sentence has two periods. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). The percent calculation must either be clearly defined within the specification or set forth within the claim.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 3-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Learner (US 2001/0024657).

Learner et al. teaches controlled-release solid compositions for the oral cavity that adheres to hard dental surfaces, such as teeth and dentures, and releases an

active pharmaceutical agent into the oral cavity (see abstract). A mixture of alcohol and water are used as the solvent to make the drug-releasing matrix (page 5, paragraph 0095-0096). The adhesive components of the compositions may be gums such as guar gum, xanthan gum, gum tragacanth and gum arabic. Active agents used for the treatment of teeth include tooth-whitening agents such as carbamide peroxide (page 10, paragraph 0207). When delivery is localized to the immediate area covered by the patch the adhesive is chosen so that the agent can penetrate the adhesive and contact the covered area in effective amounts. The amount of active agent included in the composition is generally 0.1% to about 35% (page 7, paragraph 0144-0145). The invention is described as a solid composition and dissolving the components in alcohol and water makes the compositions; therefore it is concluded the composition has less than about 10% of the hydroalcoholic component when dry. The reference also discloses within the prior art a composition comprising xanthan gum and locust bean gum used as a buccal tablet. The tablet was to be placed between the gingival surface of the jaw and the buccal mucosa where it gels to produce a soft hydrated tablet, which may be retained in position so as to provide release of etorphine for up to two hours. The buccal tablet is said to provide improved bioavailability (page 1, paragraph 0007). It can be concluded from this disclosure that this combination of gums may be used in the disclosed invention for improved bioavailabilty of the active ingredient, e.g., peroxide. The reference anticipates the claims insofar as it discloses a liquid polymer that dries into a film on the teeth comprising a mixture of adhesives and nonadhesives (including natural gums), peroxide and a hydroalcoholic component.

2) Claims 1-7 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sagel et al. (US 5,891,453).

Sagel et al. teaches oral compositions for the whitening of teeth. The oral compositions are in the form of a gel and are applied to the teeth by a strip. The gel comprises several compononents, one of which is a gelling agent. The gelling agents useful in the disclosed invention includes natural gums such as gum karaya, xanthan gum, Guar gum, gum arabic, gum tragacanth and mixtures there of. The use of the term mixtures means more than one gum may be used in the composition thereby encompassing the recited claims use of the phrase "at least two". The gelling agent is incorporated into the compositions at weight percent ranging from 0.1 to about 15% by weight of the substance (col.8, lines 31-54), which encompasses claim 2. The water content of the gel compositions ranges from 0.1% to 95% by weight of the composition (col. 9, lines 1-8). It can be concluded where the water content is fairly low the gel is fairly dry. Tooth whitening actives include peroxides, metal chlorites, perborates, percarbonates, peroxyacids and combinations thereof. Suitable peroxide compounds are hydrogen peroxide, calcium peroxide, carbamide peroxide, and mixtures thereof. The whitening active is present in an amount from about 0.01% to about 40% (col. 8, lines 1-22), as recited in claim 3. Using the range of percentages used for the peroxide and gelling agents, one can optimize the conditions to fit one's purpose. These percentages, therefore, encompass claims 14 and 15, where the ratio of gum to peroxide is from 1:25 to about 1:5. The gel is incorporated onto the polymer strip

thereby making it a bi-layer. The reference anticipates the instant claims insofar as it discloses gel comprising natural gums, peroxide and water, delivered on a flexible strip to create a film on the teeth.

3) Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Sagel et al. (US 2004/0120903).

Sagel et al. teaches whitening strips comprising films formed from a water hydratable polymer and a plasticizer. The compositions may contain several layers of film. The tooth-whitening agent is applied to one side of the film. Water hydratable polymers that may be used in the compositions include xanthan gum, guar gum and carrageanan (page 1, paragraph 0014), as recited in claims 4-5 and 10-11. The water hydratable polymer is at least about 5%, or at least about 10%, or at least about 20%, or at least about 30% and/or less than about 90%, or less than about 80%, or less than about 70% by weight of the film (page 3, paragraph 0021). Whitening agents include peroxides, metal chlorites, perborates, percarbonates, peroxyacids, persulfates, and combinations thereof. Suitable peroxide compounds include hydrogen peroxide, urea peroxide, calcium peroxide and mixtures thereof (page 2, paragraph 0015) as recited in claims 6-7 and 12-13. The concentration of the tooth whitening agent is at least about 1%, or at least about 10% or at least about 15%, or at least about 20%, or least about 25% and/or less than about 70%, or less than about 60%, or less than about 50%, or less than about 40%, or less than about 30% (page 4, paragraph 0028). The percentages disclosed by the references encompass claims 2-3 and 14-15. A method of

making the film includes dissolving the desired polymers in a solvent compatible with the polymers, i.e., water, alcohols, acetone, ethyl acetate and mixtures thereof. After a solution is formed, a plasticizer is added with stirring, followed by the addition of the whitening agent and any other ingredients such as flavors. The solution is coated onto a carrier material and dried to form a film (page 2, paragraph 0019). It can be concluded any solvent used in the procedure is less than 10%. Other ingredients that are suitable for use with the present invention include phosphates (e.g., pyrophosphates, polyphosphate, polyphosphonates, and mixtures thereof), fluoride ion sources, antimicrobial agent, anti-inflammatory agents, nutrients, and enzymes (page 4, paragraph 0026), which encompasses claim 8. The reference anticipates the instant claims insofar as it discloses mono and bi-layer films comprising gums such as xanthan and carageanan, peroxide such as hydrogen peroxide and a solvent such as water or/and alcohol that comprises less than 10% of the dry composition.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sintov et al. (US 5,425,953) in view of Learner (US 2001/0024657).

Sintov discloses liquid polymer compositions that forms films that can be used to bleach the teeth, treat dental plaque and gingivitis. In detail, the invention provides a storage stable, sustained release liquid polymer composition comprising: (a) a water-soluble cellulosic polymer; and (b) a pharmaceutically or cosmetically acceptable oxidizing (sometimes called "bleaching") agent in a pharmaceutically or cosmetically acceptable vehicle. When dry the composition forms a film. The bleaching agents in the liquid polymers include preferably a peroxide compound selected from the group consisting of hydrogen peroxide, carbamide peroxide and sodium peroxyborate monohydrate (col. 7, lines 47-51). The peroxide is included in the liquid polymer ranging from 1% to 50% w/w of the composition (col. 7, lines 62-68). The sustained-release water-soluble polymer is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl ethylcellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxyethyl methylcellulose and carboxymethyl-cellulose (col. 7, lines 2-6). The polymer is present in the compositions in a range from 5% to 15% w/w of the composition (col. 7, lines 56-61). The concentration ranges above encompass claims 2, 3, 14 and 15. Normally, changes in result effective variables are not patentable where

the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). The liquid polymer oxidizing composition can be applied to the teeth directly, being a film-forming liquid polymer solution. The film is formed by the evaporation of the solvent and once coated onto the teeth or other surface the film the oxidizing agent in a sustained-release mode, and degrades within about one hour to disappearance, after delivery of the oxidizing agent. This time frame is sufficient to provide efficacious levels of the oxidizing agent. The liquid polymer can be applied to the teeth several times per day, depending on the severity of the discoloration (col. 8, lines 11-21). The pharmaceutically or cosmetically acceptable vehicle preferably comprises an agent selected from the group consisting of water, ethyl alcohol, and ethyl alcohol and water (col. 7, lines 52-55). When dried the compositions will contain less than 10% or the alcohol and/or water. The release of peroxide from the liquid polymer compositions was studied by pouring the compositions and drying them to form a film (col. 11, lines 1-5), therefore the reference discloses a "film" as oppose to a composition as recited in the instant claims 9-13. The reference also discloses that hydrogen peroxide or peroxy compounds, which are extremely active chemicals, attack polymers. This is especially a problem in hydroalcoholic solutions and has previously precluded the delivery of oxidizing agents from film compositions. The reference differs from the instant claims insofar as it does not disclose using at least two gums in its compositions.

The secondary reference is discussed above. One specific point to remember from the reference is its disclosure of the prior art that reports a composition comprising xanthan gum and locust bean gum was used as a buccal tablet. The tablet was to be placed between the gingival surface of the jaw and the buccal mucosa where it gels to produce a soft hydrated tablet, which may be retained in position so as to provide release of etorphine for up to two hours. The buccal tablet is said to provide improved bioavailability (page 1, paragraph 0007). The reference also discloses mixtures of gums can be used as the gelling agent in the disclosed compositions. The reference differs from the instant claims insofar as it does not disclose a composition, when dried, having less than about a 10% hydroalcoholic component.

It would have been obvious to one of ordinary skill in the art to have used the xanthan gum and locust bean gum mixture as a film forming agent of the primary reference motivated by the desire to form a film with a longer sustained release time, as disclosed by the secondary reference.

Statutory-Type Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of copending Application No. 11/030845. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-15 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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